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09/744431

CERTIFICATE OF MAILING

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ELI LILLY AND COMPANY

By

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Date

5-2-01

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : James A. Hoffmann, et al.)
Serial No. : 09/744,431)
Filed : July 15, 1999) Attention:
For : FSH POLYPEPTIDES, FORMULATIONS) Branch Manager
PRODUCTS AND METHODS)
Docket No. : X-12383M)

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS

UNDER 35 U.S.C. 371

Assistant Commissioner for Patents

Washington, D. C. 20231

Sir:

In response to the "Notification of Missing Requirements dated March 28, 2001, the following is provided to conform the above-referenced application with the requirements of 37 C.F.R. §1.821 through §1.825. Enclosed herewith are:

- 1) a copy of the Notification;
- 2) a computer readable disk;
- 3) a paper copy of the sequence listing;
- 4) a statement under 1.821(f).

It is respectfully submitted the contents of the paper version of the Sequence Listing provided in the published application, filed July 15, 1999, and the computer readable form of the sequence listing are identical.

Serial No. X-12383M

It is further submitted that the incorporation of the computer readable form of the sequence listing does not represent new matter.

Respectfully submitted,



James J. Kelley
Attorney/Agent for Applicants
Registration No. 41,888
Phone: 317-277-8110

Eli Lilly and Company
Patent Division/JJK
Lilly Corporate Center
Indianapolis, Indiana 46285

19 April 2001



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|-------------------------------|-----------------------|------------------|
| U.S. APPLICATION NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 09/744431 | HOFFMANN | J |
| INTERNATIONAL APPLICATION NO. | | |
| PCT/US99/16031 | | |
| I.A. FILING DATE | PRIORITY DATE | |
| 15 JUL 99 | 23 JUL 98 | |

DATE MAILED: 28 MAR 2001

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☐ an Elected Office (37 CFR 1.495):
- ☐ U.S. Basic National Fee.
 - ☐ Copy of the international application.
 - ☐ Oath or Declaration of inventors(s).
 - ☐ Copy of Article 19 amendments.
 - ☐ Priority Document.
 - ☐ The International Preliminary Examination Report in English and its Annexes, if any.
 - ☐ Translation of Annexes to the International Preliminary Examination Report into English.
 - ☐ Indication of Small Entity Status.
 - ☐ Translation of the international application into English.
 - ☐ Translation of Article 19 amendments into English.
 - ☐ Other:
2. ☐ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.
- ☐ U.S. Basic National Fee.
 - ☐ Copy of the international application.
3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:
- ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
 - ☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
 - ☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
 - ☐ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.
 - ☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
 - ☐ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).
4. Additional claim fees of \$ _____ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.
5. ☐ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.
7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

A copy of this notice MUST be returned with this response.

- Enclosed: ☐ PCT/DO/EO/917 ☐ Notice of Defective Translation
☐ PTO-875 ☒ PCT/DO/EO/920

John L. Anderson

Telephone: 703.205.9116

FORM PCT/DO/EO/905 (March 2001)

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APR 03 2001

ELI LILLY AND CO.
PATENT DIVISION



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

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| U.S. APPLICATION NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 09/744431 | HOFFMANN | J X-12383M |

ELI LILLY AND COMPANY
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INTERNATIONAL APPLICATION NO.

PCT/US99/16031

I.A. FILING DATE

PRIORITY DATE

15 JUL 99

23 JUL 98

DATE MAILED:

28 MAR 2001

**NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS
CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE
DISCLOSURES**

Applicant has submitted papers under 35 U.S.C. 371 to enter the national stage in the United States of America. The items indicated below, however, are missing. The period within which to correct the deficiency noted below and avoid abandonment is set forth in the accompanying Notification.

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):

- ☐ The application fails to comply with the requirements of 37 CFR 1.821-1.825.
- ☐ This application does not contain, a "Sequence Listing" as a separate part of the disclosure on paper copy or compact disc, as required by 37 CFR 1.821(c).
- ☐ A copy of the "Sequence Listing" in computer readable format has not been submitted as required by 37 CFR 1.821(e).
- ☐ A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked-up copy of the "Raw Sequence Listing."
- ☐ The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- ☐ The paper copy or compact disc of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).
- ☐ Other: _____

APPLICANT MUST PROVIDE:

- ☒ An initial or substitute computer readable form (CRF) of the "Sequence Listing."
- ☐ An initial or substitute paper copy or compact disc of the "Sequence Listing," as well as an amendment directing its entry into the specification.
- ☒ A statement that the contents of the paper or compact disc and the computer readable form are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

**FOR QUESTIONS REGARDING COMPLIANCE WITH THESE REQUIREMENTS, PLEASE
CALL:**

(703) 308-4216, for Rules interpretation,
(703) 308-4212, for CRF submission help,
(703) 287-0200, for PatentIn software help.

John L. Anderson

Telephone: 703-308-9116